IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

HANNA WILKERSON,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-04505

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are the following motions brought by the defendant: (1) Motion to Exclude the General Causation Testimony of Bruce Rosenzweig, M.D. [Docket 31]; (2) Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 32]; (3) Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 34]; (4) Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [Docket 36]; (5) Motion to Exclude the Opinions and Testimony of Marvin Goldberg, Ph.D. [Docket 37]; (6) Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 41]; (7) Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 42]; (8) Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 43]; (9) Motion to Exclude the Opinions and Testimony of William Porter, M.D. [Docket 44]; (10) Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [Docket 45]; and (11) Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 50].

Also pending before the court are the following motions brought by the plaintiff: (1)

Motion to Exclude the Opinions and Testimony of Ricardo Caraballo, M.D. [Docket 38]; (2) Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [Docket 39]; (3) Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D. [Docket 40]; (4) Motion to Exclude the Opinions and Testimony of Stephen Spiegelberg, Ph.D. [Docket 47]; and (5) Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 48].

My rulings are set forth below.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 72,000 cases currently pending, approximately 16,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. In this particular case, the plaintiff, Hanna Wilkerson, was surgically implanted with the Advantage Fit System ("Advantage Fit"), a mesh product manufactured by BSC to treat SUI. Ms. Wilkerson received her surgery at Carolinas Medical Center – NorthEast in Concord, North Carolina, on March 9, 2010. (Short Form Compl. [Docket 1], at 4). She now claims that as a result of the implantation of the Advantage Fit, she has experienced various complications and injuries. The plaintiff advances the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; discovery rule, tolling, and fraudulent concealment; and punitive damages. (*Id.* at 4–5).[1] The parties have retained experts to

[1] In a Memorandum Opinion and Order entered on April 29, 2015, I dismissed Ms. Wilkerson's claims for strict liability, negligent manufacturing, breach of implied warranty of fitness for a particular purpose, and fraudulent concealment. (Mem. Op. & Order [Docket 88]). Therefore, the remaining claims in this case are negligent failure to warn, negligent design, breach of express warranty, and breach of implied warranty of merchantability. (*Id.*).

render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The Supreme Court has established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States*

v. Moreland, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, the second part of the analysis, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matters

Before I review these motions, I begin by addressing a few preliminary matters that affect many of the *Daubert* motions. First, both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[2] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective,"

[2] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his opinions—assuming the opinions are otherwise admissible—he may not be offered solely as a conduit for corporate information. There is no reason why the plaintiff requires an expert to opine on such facts.

"unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to adhere to them in this case. This does not mean, however, that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

I also note that several of the *Daubert* motions concern expert opinions entirely unrelated to the individual plaintiff at bar. For example, some experts have opined on general and specific causation with the specific causation portion of the opinion pertaining to wave plaintiffs other than Ms. Wilkerson. In addition, the parties filed a total of *sixteen Daubert* motions involving, in many instances, duplicative experts. In an effort to remedy this problem of blanketed, duplicative *Daubert* motions, I directed the parties to file disclosures, indicating who, out of the sixteen challenged experts, they plan to call at trial for each case. (*See* Pretrial Order # 121 [Docket 51], at 5–6). Through these disclosures, I hoped to gain a better understanding of the particular arguments at issue, thereby refining my *Daubert* rulings for the benefit of the transferor judge. Rather than aiding the court in this endeavor, however, the parties have effectively ignored my pretrial order, identifying fourteen of the sixteen challenged experts as probable expert witnesses. (*See* BSC's Disclosure Required by Pretrial Order # 121 [Docket 52]; Pl.'s Disclosure Required by Pretrial Order # 121 [Docket 53]). Without guidance from the parties to the contrary, I have

thus limited my review of the *Daubert* motions to only those arguments and opinions related to the instant plaintiff. In other words, I disregard arguments included in the briefing directed exclusively at other wave plaintiffs and, consequently, irrelevant to Ms. Wilkerson's case.

Finally, I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __ (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __ (S.D. W. Va. 2014), *available at* 2014 WL 5461991. The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsel's expectations that I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to entertain *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert opinions and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular opinions and objections currently before me, I assess "whether the reasoning or

methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the opinions contained therein.

Having addressed these preliminary matters, I now turn to BSC's *Daubert* motions.

IV. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Drs. Bruce Rosenzweig, Michael Thomas Margolis, Thomas H. Barker, Jerry Blaivas, Marvin Goldberg, Jimmy W. Mays, Russell Dunn, Scott Guelcher, William Porter, Richard Trepeta, and Vladimir Iakovlev.

A. Bruce Rosenzweig, M.D.

Dr. Bruce Rosenzweig is a urogynecologist and a professor of obstetrics and gynecology in Chicago, Illinois. In this case, the plaintiff offers Dr. Rosenzweig as a general causation expert on the properties of the polypropylene mesh used in the Advantage Fit, its reaction when implanted in the body, and the possible complications associated with its use to treat SUI. (*See generally* Ex. A, Rosenzweig General Expert Report [Docket 31-1]). BSC raises several objections to these opinions. Although I have considered these opinions before, Dr. Rosenzweig has since updated his expert report, and, in response, BSC has refined and reevaluated its objections. Therefore, turning to these objections, I am informed—though not bound—by my previous findings.

1. Opinions on the Biochemical Properties of Polypropylene

First, BSC argues that because Dr. Rosenzweig has no background in biochemistry or toxicology, he is not qualified to render opinions that "deal with polymer science, biochemistry

or biomaterials," such as mesh degradation or the "basic properties of polypropylene." (BSC's Mot. to Exclude the General Causation Test. of Dr. Bruce Rosenzweig, M.D. and Mem. in Supp. ("BSC's Mot. re: Rosenzweig") [Docket 31], at 6–7). With respect to the qualifications prong of Federal Rule of Evidence 702, the Fourth Circuit Court of Appeals has held that "[o]ne knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989); *see also id.* ("[T]he test for exclusion is a strict one."). Here, although Dr. Rosenzweig may not know the precisions of oxidative degradation, Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body. He has performed "over a thousand pelvic floor surgical procedures," as well as "close to 300 surgeries dealing with complications related to synthetic mesh." (Ex. A, Rosenzweig General Expert Report [Docket 31-1], at 1–2). And as he explained during his deposition, "I have explanted mesh. I have seen degraded mesh. I've seen hardened, brittled, fragmented mesh upon removal of mesh." (Ex. B, Rosenzweig Dep. [Docket 31-2], at 24:23–25:1). Furthermore, Dr. Rosenzweig has read "close to the 2,000 papers that have been generated on midurethral slings." (*Id.* at 19:6–11). Dr. Rosenzweig's established background and skill in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process, even though his knowledge about the precise biochemical interactions involved might not be as extensive as that of others. *See* Fed. R. Evid. 702 (stating that an expert witness may be qualified "by knowledge, skill, experience, training, or education"); *see also Pineda v. Ford Motor Co.*, 52 F.3d 237, 244 (3d Cir. 2008) (holding that a court should not exclude testimony "simply because [it] does not deem the proposed expert to be the best qualified or because the expert does not have the specialization that the court considers

most appropriate"). Any gaps in Dr. Rosenzweig's knowledge go to his credibility, not his admissibility as an expert.

BSC also contends that Dr. Rosenzweig has not provided a reliable basis for his opinions regarding the properties of polypropylene mesh and has instead solely relied on "gross examination" of his patients. (BSC's Mem. re: Rosenzweig [Docket 31], at 8). I disagree. In addition to the examination of his patients over the past twenty years, Dr. Rosenzweig relied on dozens of scientific articles concerning the degradation of polypropylene in reaching his opinion that mesh degrades. (*See generally* Ex. A, Rosenzweig General Expert Report [Docket 31-1]; *see also* Ex. B, Rosenzweig Dep. [Docket 71-2], at 18:22–19:11 (explaining that he has read the entirety of all the materials he relied on in forming his opinions)). Dr. Rosenzweig explained this methodology during his deposition:

> It's the same methodology that I use when I'm investigating any clinical process. I look at, first of all, my clinical experience. I look at the literature. I went through the literature and found various articles that discuss this. I went to their references. I looked at those articles to be able to get a concise basis for the opinions that I have.

(*Id.* at 125:19–126:2). Dr. Rosenzweig's methodology is more than "gross examination" of mesh. Indeed, this court, as well as other courts, has accepted this methodology as reliable in similar circumstances. *See, e.g.*, *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1370–71 (M.D. Ga. 2010) (finding that experts' reliance on their urogynecological experience, scientific literature, and case reports in reaching their opinions satisfied Rule 702).

For these reasons, I find Dr. Rosenzweig qualified to opine on mesh degradation and the properties of polypropylene, and I further find that his opinions are supported by a reliable methodology. Therefore, I **DENY** BSC's motion on this matter.

2. Opinions on Product Design

BSC next argues that Dr. Rosenzweig is not qualified to opine on the design of the Advantage Fit because "he has no experience designing implantable medical devices like vaginal mesh." (BSC's Mot. re: Rosenzweig [Docket 31], at 10). Therefore, in BSC's view, Dr. Rosenzweig's opinions on the suitability of mesh as a permanent implant should be excluded. The analysis set forth in the above section leads me to again disagree with BSC.

Although Dr. Rosenzweig has never designed vaginal mesh devices, he has considerable familiarity with their structure and use. First, over the course of his career as a pelvic surgeon, he has accumulated an abundance of knowledge about the use of various surgical procedures in the treatment of SUI, including the implantation of midurethral slings like the Advantage Fit. (*See* Ex. A, Rosenzweig General Expert Report [Docket 31-1], at 6–9 (describing the Burch procedure, pubovaginal sling procedures, and midurethral sling procedures)). Second, Dr. Rosenzweig received thorough training on the implantation of sling products in pelvic repair. (*See id.* at 2 (stating that he attended three training seminars on the use of synthetic mesh devices, which were organized by the product manufacturers)). Third, Dr. Rosenzweig has performed these procedures countless times. (*See id.* 1–2 (stating that he has performed "over a thousand pelvic floor surgical procedures," as well as "close to 300 surgeries dealing with complications related to synthetic mesh")). And finally, Dr. Rosenzweig has invented a catheter device, which reinforces his background in the design and use of surgical products. (Ex. B, Rosenzweig Dep. [Docket 31-2], at 241:12–14). This knowledge, training, and experience with product design, specifically the design of BSC's midurethral slings, qualify Dr. Rosenzweig to opine on the design of the Advantage Fit and the polypropylene used to construct it. *See* Fed. R. Evid. 702 (stating that a witness may be "qualified as an expert by knowledge, skill, experience,

training, or education"); *see also, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (ruling that a urogynecologist was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders").

Furthermore, contrary to BSC's contentions, Dr. Rosenzweig has a reliable basis for his opinions on the Advantage Fit product design. He considered more than internal corporate documents in arriving at his opinion on the design of the Advantage Fit, incorporating his experience and citing to relevant and persuasive scientific literature. (Ex. A, Rosenzweig General Expert Report [Docket 31-1], at 18–23; *see also* Rosenzweig Dep. [Docket 71-2], at 18:11–19 (explaining that he relied on the "most authoritative" articles)). This detailed examination of the literature in light of his first-hand experience with mesh devices satisfies the reliability requirements of *Daubert*. *See, e.g.*, *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d at 1370–71 (finding that experts' reliance on their urogynecological experience, scientific literature, and case reports in reaching their opinions satisfied Rule 702).

Accordingly, I decline to exclude Dr. Rosenzweig's opinions on product design, and BSC's motion on this point is **DENIED**.

3. Opinions on Product Testing

Next, BSC asks this court to exclude Dr. Rosenzweig's opinions on the testing of mesh products, including his opinions that BSC "should have conducted testing to determine if mesh would degrade in the body"; BSC "did not undertake long term testing to determine if warnings in the MSDS were associated with long term consequences"; BSC "'should have' conducted clinical trials prior to marketing its product"; and BSC's "registry of 2,015 patients was not adequate to provide reliable information on safety/efficacy of its products." (BSC's Mot. re:

Rosenzweig [Docket 31], at 10–11 (quoting Ex. A, Rosenzweig General Expert Report [Docket 31-1], at 13–38)). According to BSC, Dr. Rosenzweig lacks the qualifications to opine on these matters. While Dr. Rosenzweig has years of experience operating with polypropylene mesh products, his expert report does not convey any similar experience, education, or knowledge about the appropriate testing a medical device manufacturer should perform on its products prior to sale. The plaintiff's response does not allude to any relevant experiences either. Therefore, I agree with BSC and find Dr. Rosenzweig unqualified to testify on the adequacy or inadequacy of BSC's product testing. *See* Fed. R. Evid. 702 (providing that a witness can provide expert opinions only if he is "qualified as an expert by knowledge, skill, experience, training, or education"). This part of BSC's motion is thus **GRANTED**.

4. Opinions on the Advantage Fit Directions for Use ("DFU")

BSC also argues that because Dr. Rosenzweig does not have "experience personally drafting product label[s]," he is unqualified to opine on the adequacy of the warnings contained in the Advantage Fit DFU. I have previously considered whether experience as a urogynecologist can qualify a witness to opine on the sufficiency of a DFU, and my conclusion has been affirmative to a certain extent:

> [A urogynecologist who] has no demonstrated experience in the requirements for medical device labels cannot testify as to what the [product] label should or should not have included under the law. However, as an experienced urogynecologist, he may testify about the risks he perceives that the [product] poses to patients and then opine that the [product's DFU] did not convey those risks. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (internal quotations and brackets omitted)).

Wise v. C.R. Bard, Inc., No. 2:12-CV-01378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). I adopt this reasoning here. Without experience or background in the legal requirements

for medical device warnings, Dr. Rosenzweig is qualified to opine on the content of the DFU only to the extent that his opinions fit within the comparison described in *In re Yasmin*. Trusting that Dr. Rosenzweig's testimony at trial will be limited accordingly, I **DENY** BSC's motion on this matter.

5. Opinions on a Link Between Cancer and Polypropylene Mesh

During his deposition, Dr. Rosenzweig offered the opinion that there is "an association" between cancer and polypropylene. (Ex. B, Rosenzweig Dep. [Docket 31-2], at 147:4–9). BSC moves to exclude this opinion as irrelevant and prejudicial. Because Ms. Wilkerson does not claim that the Advantage Fit sling has caused her to contract cancer, I agree with BSC. Rule 702 requires expert opinion testimony to "help the trier of fact to understand the evidence or to determine a fact at issue," Fed. R. Evid. 702, and the carcinogenicity of mesh is not a fact at issue. Any association between polypropylene mesh and cancer, therefore, would "confuse the jury on a matter with scant probative value." *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *38 (S.D. W. Va. 2014), *available at* 2014 WL 5320566 (internal quotations omitted). All of Dr. Rosenzweig's opinions on this matter are therefore **EXCLUDED**.

6. Opinions on the Material Safety Data Sheet ("MSDS") for Polypropylene

Finally, BSC objects to Dr. Rosenzweig's opinion that the Advantage Fit "should not be used in the body because the manufacturer of the raw polypropylene has included in its MSDS a medical application caution stating that the material should not be permanently implanted in the body." (BSC's Mot. re: Rosenzweig [Docket 31], at 14 (citing to Ex. A, Rosenzweig General Expert Report [Docket 31-1], at 14–18)). BSC claims that this opinion is irrelevant, given that the purpose of an MSDS is to communicate "workplace chemical hazards to employers and employees," rather than to the consumers of medical products. (*Id.*). In response, the plaintiff

simply refers to this court's prior order, in which I found a urogynecologist qualified to testify that by omitting the MSDS, the product's DFU did not adequately inform physicians about the product's risks. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D. W. Va. 2014) (finding Dr. Blaivas qualified to opine on "the extent to which any inaccuracies or omissions [in the DFU] could either deprive a reader or mislead a reader [about] the risks and benefits of the [product]" (internal quotations omitted)).

Dr. Rosenzweig's opinion about the MSDS, however, goes beyond what was allowed by my prior ruling and enters subject matters about which he is not qualified to testify. Specifically, Dr. Rosenzweig concludes that BSC did not perform the "clinically relevant" and "long term" testing that it should have to investigate the MSDS warning. (Ex. A, Rosenzweig General Expert Report [Docket 31-1], at 17–18). As explained above, Dr. Rosenzweig lacks the experience and knowledge necessary to opine on what testing a manufacturer should perform on his products. These opinions, therefore, are **EXCLUDED**.[3]

In sum, BSC's Motion to Exclude the General Causation Testimony of Dr. Bruce Rosenzweig [Docket 31] is **GRANTED in part** and **DENIED in part**.

B. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation opinions in this case. (*See* Ex. A, Margolis Report [Docket 32-1], at 1–26). BSC argues that his opinions are unreliable because he failed to consider contrary scientific literature and failed to provide any scientific

[3] BSC also asks this court to exclude Dr. Rosenzweig's opinion that the Advantage Fit should not be used in the body because it is based on the irrelevant information contained in the MSDS. Because Dr. Rosenzweig has used other sources aside from the MSDS to support his opinion about the suitability of polypropylene as a medical implant, I do not exclude it on these grounds. *See supra* § IV.A.1 (finding that Dr. Rosenzweig applied a reliable methodology to reach his opinions on mesh degradation, the properties of polypropylene, and the design of the Advantage Fit supported by a reliable methodology). I note, however, that reference to the MSDS in support of this opinion will not be allowed at trial—Dr. Rosenzweig has no reliable basis to conclude that the cautionary language in the MSDS was based on medical concerns as opposed to liability concerns.

basis for his other opinions. Also, BSC argues that Dr. Margolis seeks to offer opinions beyond his expertise.

1. BSC Argues that Dr. Margolis Failed to Consider Contrary Scientific Studies in Forming His Opinions

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)); *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009), *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

a. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe and Effective for SUI

BSC argues that Dr. Margolis's opinion that polypropylene mid-urethral slings are not safe and effective for the treatment of SUI is unreliable because he ignored peer-reviewed literature indicating otherwise. I do not doubt that Dr. Margolis looked at contrary studies.

However, his method may be unreliable if he failed to provide a scientific basis for rejecting those studies.

In the expert materials before the court in this case, Dr. Margolis provides a sufficiently thorough explanation as to why he discounted certain literature, including discussions of bias in corporate-sponsored studies. (*See, e.g.*, Ex. A, Margolis Report [Docket 32-1], at 21; Ex. B, Margolis Dep. (Dec. 28, 2014) [Docket 72-2], at 218:9–219:20, 232:2–11). In her response, the plaintiff also cites to articles in support of Dr. Margolis's explanation. (Pl.'s Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. ("Pl.'s Resp. re: Margolis") [Docket 72], at 6–7). Moreover, Dr. Margolis's report particularly describes his basis for rejecting the *Nilsson* study. (Ex. A, Margolis Report [Docket 32-1], at 21). Therefore, I do not exclude Dr. Margolis's opinion based on reliability. BSC's motion with respect to this opinion is **DENIED**. Whether Dr. Margolis's reasons for rejecting certain studies are accurate or whether Dr. Margolis inconsistently applies these reasons to the literature are appropriate topics for cross-examination.

b. Opinion Regarding the Complication Rates of Pain in Women with Polypropylene Mesh and Slings

BSC next challenges Dr. Margolis's opinion that there is a greater than 50% complication rate of pain in women with polypropylene mesh and slings. BSC contends that he fails to provide a scientific basis for disagreeing with studies that find lower pain rates. Dr. Margolis merely discounts those studies "[b]ecause that's not what [he] ha[s] seen, read, studied, observed, and that's not biologically plausible." (*See* Ex. E, Margolis Dep. (Jan. 6, 2014) [Docket 32-2], at 239:11–13).

In his deposition, Dr. Margolis acknowledges that contrary studies exist, (*see id.* at 239:2–6), and I do not doubt that Dr. Margolis reviewed contrary studies. However, his

methodology may be flawed if he does not provide an adequate explanation for why he disagrees with those studies. The plaintiff has failed to identify such an explanation in this case. Therefore, Dr. Margolis's opinion that more than 50% of women implanted with mesh experience pain is **EXCLUDED** as unreliable. This aspect of BSC's motion is **GRANTED**.

c. Opinions Regarding General Complication Rates in Women with Polypropylene Mesh

BSC also challenges Dr. Margolis's general opinions that complications in women with polypropylene mesh products are high. BSC contends that Dr. Margolis disregards literature revealing single digit dyspareunia complication rates without sufficient explanation. In his deposition, Dr. Margolis discounts these studies by alleging that the complications are underreported, that the studies are inaccurate, and that the data is possibly fabricated. (*Id.* at 241:12–20). Moreover, Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." (*Id.* at 259:8–9). In other words, he "assume[s] the worse-case scenario" and errs on the side of opining as to a higher complication rate to better protect a patient. (*Id.* at 259:11–19). "[G]iv[ing] the benefit of the doubt to the patient" is not a reliable, scientific basis for determining the complication rates associated with a mesh device. (*Id.* at 259:8–9). The plaintiff has failed to demonstrate that Dr. Margolis has sufficient scientific support to opine as to these generalized statements. Therefore, this testimony is **EXCLUDED**, and this part of BSC's motion is **GRANTED**.

2. BSC Argues That Dr. Margolis Failed to Provide Any Scientific Basis For His Other Opinions

BSC also argues that Dr. Margolis failed to provide any scientific basis for his other opinions and that he based these opinions on his personal experience alone. The plaintiff does

not address the majority of BSC's arguments here. Instead, in a generalized fashion, she states in a paragraph that Dr. Margolis should be allowed to testify about his personal experience. (Pl.'s Resp. re: Margolis [Docket 72], at 15). BSC interprets such a response as the plaintiff's concession.

I decline to raise counterarguments for the plaintiff when she has failed to address BSC's arguments in her briefing. Dr. Margolis may not solely rely on his personal observations, especially when he seeks to provide broad opinions, such as the infection rate in women with mesh. *See Daubert*, 509 U.S. at 592 (stating that Rule 702 permits "an expert [to offer] wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation" due to the "assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline"). "Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Id.* at 590. The plaintiff has not "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Therefore, the following opinions from Dr. Margolis are **EXCLUDED**: (1) that the Burch procedure is more effective than polypropylene mesh slings;[4] (2) that Xenform slings are more effective than polypropylene slings; (3) that the infection rate of polypropylene mesh is up to 100%; (4) that the complication rate of urethral obstruction is greater than 10% with polypropylene mid-urethral slings; and (5) that he has removed 10 to 15% of BSC products. These portions of BSC's motion are **GRANTED**.[5]

[4] *See supra* at 7.

[5] I have previously excluded opinions (2) through (5) on reliability grounds. *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *16–18 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *10–12 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *see Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *12–13 (S.D. W. Va. 2014), *available at* 2014 WL 5461991 (addressing only opinions (3) and (5)).

Unlike the above opinions, the plaintiff appears to respond to BSC's argument concerning Dr. Margolis's opinion about a lack of scientific support for the use of mesh. In his report, Dr. Margolis opines that there is a lack of sound scientific data supporting the use of mesh in the treatment of both SUI and POP. (Ex. A, Margolis Report [Docket 32-1], at 21). First, I **EXCLUDE** this opinion with respect to POP because it is irrelevant to this SUI case.[6]

As for the reliability of this opinion with respect to SUI, BSC contends that Dr. Margolis's opinion should be excluded because Dr. Margolis contradicted himself during his deposition. In response, the plaintiff argues that BSC misinterprets Dr. Margolis. The plaintiff contends that Dr. Margolis merely opines that there is a lack of *long-term* data. Contradictions in testimony should be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994) ("[E]valuating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses . . . ."). Therefore, I do not exclude Dr. Margolis's opinion on a lack of *long-term* data on reliability grounds.[7] Therefore, BSC's motion regarding this opinion is **GRANTED in part**, with respect to Dr. Margolis's opinion on this matter concerning POP, and **DENIED in part**, with respect to Dr. Margolis's opinion on this matter concerning SUI.

---

[6] I note that BSC's motion only challenges this opinion with respect to SUI. (BSC's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. ("BSC's Mem. re: Margolis") [Docket 33], at 12). However, the plaintiff in her response and BSC in its reply argue as if BSC had challenged this opinion with respect to POP as well.

[7] The plaintiffs in prior cases have responded to this same challenge in a different way. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *9 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *11 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. Instead of focusing on long-term data, those plaintiffs informed the court that Dr. Margolis never opined that there was *no* data supporting the benefits of polypropylene mesh, but just that there was no *credible* data on this subject. In those cases, I excluded Dr. Margolis's opinion because "it [was] still unclear why Dr. Margolis believe[d] th[o]se studies lack[ed] credibility." *Sanchez*, 2014 WL 4851989, at *14.

3. BSC Argues that Dr. Margolis's Opinions are Outside His Area of Expertise

BSC argues that Dr. Margolis offers opinions outside the scope of his qualifications on "(1) biomaterials; (2) polypropylene degradation; (3) chronic foreign body reaction; (4) adequate pore size; (5) adequate weight of polypropylene; (6) biocompatibility of polypropylene; (7) medical device design and development; and/or (8) marketing." (BSC's Mem. re: Margolis [Docket 33], at 15). In her response, the plaintiff states that "[t]o the extent that Dr. Margolis' opinions regarding biomaterials, medical device design, development, and marketing are outside of his expertise and experience, Dr. Margolis will be instructed to limit his opinion and avoid these areas. However, Plaintiffs' [sic] stipulation is only as to these limited areas outside of his expertise." (Pl.'s Resp. re: Margolis [Docket 72], at 15).

In its reply, BSC states that this concession is "unclear[.]" (BSC's Mem. of Law in Reply to Pl.'s Opp'n to Def.'s Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. [Docket 74], at 5). I find that the plaintiff's response explicitly concedes that Dr. Margolis will not offer opinions on topics 1, 7, and 8 listed by BSC. Further, the remaining topics 2 through 6 fit within at least one of the categories listed by the plaintiff. (Pl.'s Resp. re: Margolis [Docket 72], at 15). In terms of the concession's qualifying language—*i.e.*, to the extent these subjects are outside of Dr. Margolis's expertise, "Dr. Margolis will be instructed to limit his opinion and avoid these areas," (*id.*)—the court declines to engage in analyzing the plaintiff's intentional ambiguity. The plaintiff fails to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that "Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products." (*Id.*). I need not make such arguments for them. Therefore, this aspect of BSC's motion is **GRANTED**.

4. Opinions Offered by Dr. Margolis That Were Not Disclosed in His Expert Report

Finally, BSC argues that Dr. Margolis seeks to offer opinions that were not disclosed in his expert report and that Dr. Margolis seeks to discuss materials that were not cited to in his expert report. Rule 26 requires an expert report to contain "a complete statement of all opinions the witness will express and the basis and reasons for them[.]" Fed. R. Civ. P. 26(a)(2)(B)(i). The plaintiff does not provide a response to this argument.

First, BSC notes that Dr. Margolis's expert report does not include his opinions "on the preferred weight of mesh and immune system response[.]" (BSC's Mem. re: Margolis [Docket 33], at 17). I disagree. In his report, Dr. Margolis notes several BSC documents discussing the weight of mesh and other mesh design features. (*See* Ex. A, Margolis Report [Docket 32-1], at 11-13). Then, Dr. Margolis states:

> I agree with the statements made from Boston Scientific in its 2012 National Sales Meeting memo in that polypropylene mesh is not inert within the body, mesh shrinkage of up to 20–50% occurs, surface area is directly related to subsequent infection and complications, *a reduction in materials that come in contact with the body reduces foreign body reactions and complications*, nerve destruction by mesh leads to chronic pain, and that shrinkage of connective tissue formation (scarring and bridging) leads to complications including pain.

(*Id.* at 13 (emphasis added)). Thus, I find that Dr. Margolis's opinions on the weight of mesh and the associated complications are sufficiently disclosed. I decline to exclude his opinions on this matter on Rule 26 grounds.

BSC also argues that Dr. Margolis cited at his deposition "to a power point presentation and over 16 new articles that were not included in his report or the attachments thereto." (BSC's Mem. re: Margolis [Docket 33], at 17). BSC attaches to its motion a list of five deposition transcripts, one U.S. Patent Publication, thirty six BSC documents, and forty two scientific articles that were not included in Dr. Margolis's expert report or relied-upon list. (Ex. G, Margolis Nondisclosure List [Docket 32-2], at 1–6). Testimony on direct examination using such

undisclosed sources as support for his opinions is **EXCLUDED** on Rule 26 grounds. However, the court notes that the following articles that BSC alleges were not disclosed are, in fact, included in Dr. Margolis's relied-upon list: (1) Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*; (2) Maher, C., et al., *Surgical management of pelvic organ prolapse in women*. (*See* Ex. A, Margolis Report, [Docket 32-1], at App. C). Dr. Margolis's testimony on these two articles is not excluded under *Daubert*.[8]

Therefore, I find that such aspect of BSC's motion is **GRANTED in part** and **DENIED in part**.

For the reasons stated above, I **GRANT in part** and **DENY in part** BSC's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 32].

C. Thomas H. Barker, Ph.D.

The plaintiff offers Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing. (*See* Ex. D, Barker Report [Docket 34-1], at 4–7). BSC argues that Dr. Barker's opinions are unreliable because he lacks sufficient scientific support and because his opinions are litigation driven. BSC also contends that Dr. Barker is unqualified to opine on polypropylene generally and on design and testing. In forming his opinions, Dr. Barker relied upon the scientific literature, his experience, and corporate documents. (*See id.* at Ex. B (relied-upon list)).

1. Reliability

[8] BSC also states that any opinions that Dr. Margolis based on Laura Angelini's deposition should be excluded because the transcript "was not produced and plaintiffs' [sic] counsel would not agree to produce it." (BSC's Mem. re: Margolis [Docket 33], at 18). I decline to exclude these opinions on Rule 26 grounds. Laura Angelini's deposition is listed in Dr. Margolis's relied-upon list attached to his Rule 26 expert report. (Ex. A, Margolis Report [Docket 32-1], at App. C). Whether or not the plaintiff's counsel will provide BSC with this transcript is a discovery matter.

a. Opinion on a Mechanical Mismatch Between Mesh and the Human Body

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. (*See, e.g.*, Ex. D, Barker Report [Docket 34-1], at 5). I find this opinion to be unreliable. In comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding 6 to 7 kilopascals for vaginal tissue. (Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 34-1], at 84:13–16). However, he admits that he has no scientific basis for forming a kilopascal number for BSC mesh. (*Id.* at 105:3–14). Moreover, Dr. Barker admits that, although "[t]here's significant evidence in the medical literature that there are regimes that the mesh is not mechanically matched with vaginal tissue . . . the studies were never done, so we can't say for sure." (*Id.* at 108:10–22). He also testifies that "there's certainly data to suggest that the mesh gets significantly stiff under load" but then concedes that, "without proper testing, it's everyone's guess." (*Id.* at 111:13–14). Such an opinion rests on an unreliable basis. To the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**.

b. Opinions on the Clinical Significance of His Mechanical Performance Findings

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are **EXCLUDED** as unreliable as well. (*See, e.g.*, Ex. D, Barker Report [Docket 34-1], at 6–7). His opinion on the mechanical mismatch generally is excluded, and, thus, any derivative opinions of such are also unreliable. Dr. Barker testified that testing would need to be done in order to determine the effect that an implant may have in vivo. (*See* Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 34-1], at 97:21–1). However, he also states that no one has performed this testing for transvaginal mesh. (*See id.* at 98:2–7).

Concluding that mesh degrades, deforms, or causes scarring in the human body based on speculation that there is a mechanical mismatch between vaginal tissue and BSC mesh fails to survive *Daubert* scrutiny. Moreover, in forming these in vivo opinions, Dr. Barker relied on a mesh study performed ex vivo, where the authors explicitly state that their study does not conclusively reveal the mesh's behavior in the human body. (*See* Ex. F, Shepard, JP et al., *Uniaxial Biomechanical Properties of Seven Different Vaginally Implanted Meshes for Pelvic Organ Prolapse*, 23 Int'l Urogynecology J. 613, 619 (2012) [Docket 80-1] (stating that "the experimental setup allows us to draw only preliminary conclusions about the various meshes")). Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately 35% to 52% of deformation in its mesh samples. (Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 34-1], at 135:14–136:3). Dr. Barker bases this opinion on a BSC email. However, when questioned about this topic, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. (*See id.* at 137:15–138:2). This deposition testimony further reveals the unreliability of Dr. Barker's methodology. BSC's motion with respect to Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue is **GRANTED**.[9]

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 34] is **GRANTED**.[10]

[9] In her response, the plaintiff contends that BSC does not challenge Dr. Barker's opinions "that the mesh used in the BSC products was not designed to maintain its properties when placed in the body" and that the "biocompatibility of a specific biomaterial is specific to a particular area of the body, which will respond in its own particular fashion." (Pl.'s Opp'n to Def. BSC's Mot. & Mem. of Law in Supp. to Exclude Ops. & Test. of Dr. Thomas Barker, Ph.D. [Docket 64], at 11). However, this statement is incorrect. BSC addresses these two opinions in its original motion, when challenging Dr. Barker's opinions on the clinical significance of a mechanical mismatch.

[10] As for qualifications, Dr. Barker holds a Ph.D. in biomedical engineering and is currently on the faculty of a joint department within the Georgia Institute of Technology and Emory University School of Medicine. He states in his

D. Jerry Blaivas, M.D.

Dr. Blaivas is a pelvic surgeon and urologist. (Ex. A, Blaivas Obtryx Report [Docket 36-1], at 1).[11] The plaintiff offers Dr. Blaivas to opine as to general causation.[12] He renders several opinions, including those related to the complications associated with polypropylene mesh slings and the Obtryx, the safety and efficacy of synthetic slings as compared to non-mesh procedures, and BSC's warnings to physicians and patients. (*See id.* at 3–5). BSC argues that Dr. Blaivas's testimony should be excluded on reliability and qualifications grounds.[13]

---

expert report that his research focuses on

> the effects of mechanical forces and tissue/material mechanical properties (e.g. stiffness) on the host response. I am trained and have extensive expertise in the evaluation of biomaterial mechanical properties, biomaterial/implant design, the foreign body host response, and human tissues under repair and fibrosis, including analyses of cell/molecular biological outcomes.

(Ex. D, Barker Report [Docket 34-1], at 3). Dr. Barker conducted postdoctoral research focusing on "exploring the mechanisms of biomaterial associated fibrosis (e.g. the foreign body response)." (*Id.* at 2). Additionally, Dr. Barker has authored several book chapters and peer-reviewed articles. (*Id.* at 3).

I do not doubt Dr. Barker's qualifications in the field of biomedical engineering. However, I need not address them because I find Dr. Barker's opinions to be unreliable. Even if an expert is highly qualified, an analysis of the reliability of that expert's methodology is required. *See Daubert*, 509 U.S. at 597 (explaining that the Federal Rules of Evidence "do assign the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). Qualifications alone do not guarantee reliability. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3–5 (S.D. W. Va. Oct. 11, 2007) (excluding opinions of a "very qualified" expert because the basis for the testimony was unreliable). "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Daubert*, 509 U.S. at 590.

[11] BSC has attached several of Dr. Blaivas's expert reports to their motion, only one of which applies to this case. (*See* Ex. A, Blaivas Obtryx Report [Docket 36-1], at 1 (report which "RELATES TO: ALL BOSTON SCIENTIFIC WAVE I AND II CASES INVOLVING AN OBTRYX SLING")).

[12] Neither BSC nor the plaintiff attaches Dr. Blaivas's reliance list to his Obtryx expert report, even though Dr. Blaivas writes that, "[i]n addition to the references included herein, an Index is attached hereto and by reference made a part hereof. Please see Exhibit 'C' attached." (Ex. A, Blaivas Obtryx Report [Docket 36-1], at 22). There is an Exhibit C reliance list attached to Dr. Blaivas's expert report for the case of *Barden, et al. v. Boston Scientific Corp.*, Case No. 2:13-cv-05091, which BSC also attached to its motion in the instant case. (*See* Ex. C, Blaivas *Barden* Report [Docket 36-1], at Ex. C). However, the court is unclear as to whether that particular reliance list also applies to Dr. Blaivas's Obtryx report. Nevertheless, Dr. Blaivas's *reference* list for the Obtryx report lists several sources and studies that he considered. (*See* Ex. A, Blaivas Obtryx Report [Docket 36-1], at 17-21 (reference list for Obtryx report)). Thus, the court finds such lack of additional reliance list to have no effect on its decision here.

[13] In its motion, BSC states that it

> incorporates by reference its arguments against Dr. Blaivas's general causation opinions stated in its earlier *Daubert* motion, Case No. 2:12-cv-08633, Dkt. No. 239 and anticipates that the Court will reach the same conclusions here. Boston Scientific addresses Dr. Blaivas's general causation opinions to the extent Dr. Blaivas's testimony has highlighted additional methodological flaws and to identify opinions that the Court has excluded and should exclude

1. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe in the Treatment of SUI

BSC challenges Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI. BSC first contends that such an opinion is unreliable because Dr. Blaivas formed this opinion based on his subjective belief. However, the court need not evaluate such an argument because I **EXCLUDE** Dr. Blaivas's opinion based on BSC's second argument—that, in forming this opinion as a trial expert, Dr. Blaivas applied standards different than those he applies in his medical practice. In his deposition, Dr. Blaivas was confronted with a statement he had previously made in a peer-reviewed article that contradicts his safety opinion proffered in this case—namely, "The etiology of mesh sling complications is a matter of conjecture." (Ex. N, Blaivas Dep. (Dec. 15, 2014) [Docket 36-2], at 392:8–12). Dr. Blaivas explains that "I phrase my words differently in the peer-reviewed literature than I do in the legal literature because it's two different sets of rules." (*Id.* at 391:20–24). He states, "I can offer a different opinion with a reasonable degree of medical certainty than I can in the peer-reviewed literature which requires, in my judgment, a higher degree of certainty than a reasonable degree." (*Id.* at 391:14–19).

The Supreme Court has said that "[t]he objective of [the *Daubert* gatekeeping] requirement . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Although the plaintiff attempts to persuade the court otherwise, the above deposition testimony plainly reveals that Dr. Blaivas employed less intellectual rigor in

---

again.

(BSC's Mot. & Mem. of Law in Supp. to Exclude the Ops. & Test. of Jerry Blaivas, M.D. ("BSC's Mot.") [Docket 36], at 2). However, a new expert report and new deposition testimony of Dr. Blaivas are before the court in this case. As I state above, counsel's expectations that I align with my previous rulings when faced with a different record are remiss.

forming this opinion as an expert witness than he employs when writing studies in his field. Such admission renders Dr. Blaivas's methodology unreliable. As a result, BSC's motion with respect to this opinion is **GRANTED.**[14]

2. Opinion on Design of Polypropylene Mesh Slings

Next, BSC challenges Dr. Blaivas's opinion on the design of polypropylene mesh slings. (BSC's Mot. [Docket 36], at 9 (quoting Ex. A, Obtryx Report [Docket 36-1], at 6 stating, "A permanent implantable device, such as the Obtryx, Obtryx Curved and Obtryx Halo, should not have been designed for placement in a surgically contaminated field . . . .")). BSC contends that this opinion should be excluded because (1) "Dr. Blaivas has no specialized training or education that qualifies him to offer opinions on product design," (2) "he has no experience implanting an Obtryx," and (3) "[t]he Court has previously held that Dr. Blaivas is not qualified to opine on product design, and the court should exclude his design opinions here." (*Id.* at 8–9 (citing court's prior order)). Although BSC's third contention is not a *Daubert* argument, I agree with BSC that Dr. Blaivas lacks qualifications to be deemed an expert in the design of a medical device. The plaintiff contends that Dr. Blaivas's surgical experience with similar slings renders him qualified. (Pl.'s Opp'n to BSC's Mot. & Mem. in Supp. to Exclude the Ops. & Test. of Jerry Blaivas, M.D. ("Pl.'s Resp.") [Docket 65], at 9–10). However, this experience alone insufficiently establishes his design qualifications. Thus, his opinions related to product design are **EXCLUDED**.

3. BSC Alleges that Dr. Blaivas Seeks to Offer Opinions Outside Area of Expertise

BSC argues that Dr. Blaivas seeks to offer opinions on mesh shrinkage, degradation, and the MSDS that are outside his area of expertise. Above, I exclude Dr. Blaivas's opinion that

[14] *See supra* at 7.

polypropylene mid-urethral slings are not safe in the treatment of SUI on reliability grounds. Therefore, I need not address Dr. Blaivas's qualifications on shrinkage and degradation.

As for the MSDS, BSC seeks to exclude Dr. Blaivas's opinion that "[t]he polypropylene mesh used in the Obtryx, Obtryx Curved and Obtryx Halo was never meant to be implanted inside the human body per the applicable Material Safety Data Sheet ('MSDS')." (Ex. A, Blaivas Obtryx Report [Docket 36-1], at 5). The plaintiff fails to respond to this argument, and I presume that the plaintiff concedes that Dr. Blaivas will not offer such an opinion at trial. I decline to raise counterarguments on her behalf. Thus, BSC's motion with respect to Dr. Blaivas's MSDS opinion is **GRANTED**.

4. Specific Causation

Although BSC argues that Dr. Blaivas's specific causation opinions should be excluded, Dr. Blaivas is not a specific causation expert in this case. (*See* BSC's Reply in Supp. of Its Mot. to Exclude the Ops. & Test. of Jerry Blaivas, M.D. [Docket 78], at 10 n.34). Therefore, BSC's motion with respect to this matter is **DENIED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [Docket 36] is **GRANTED in part** and **DENIED in part**.

E. Marvin Goldberg, Ph.D.

The plaintiff has indicated that she does not intend to call Dr. Goldberg at trial. (Disclosure Required by Pretrial Order # 121 [Docket 53]). Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Marvin Goldberg, Ph.D. [Docket 37] is **DENIED as moot**.

F. Jimmy W. Mays, Ph.D.

Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee who

offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on the polypropylene implant. Dr. Mays's opinions are based upon his experience, knowledge, and references to scientific literature. Additionally, Dr. Mays tested the chemical and thermal properties of seven BSC pelvic repair meshes, including the Advantage Fit, and compared the results to four commercial isotactic polypropylene resins. Specifically, BSC takes issue with Dr. Mays's thermogravimetric analysis ("TGA"), which is a common method used for studying the thermo-oxidative stability of polymers.[15]

BSC seeks to exclude Dr. Mays's opinions based on his TGA because they are unreliable and irrelevant. By way of background, Dr. Mays performed TGA on seven exemplars in the air and compared their thermo-oxidative stability to that of four commercial polypropylene resins, all of which were stabilized with anti-oxidants. (Ex. B, Mays Report [Docket 43-2], at 17). Dr. Mays also removed the anti-oxidants from one Pinnacle exemplar to examine how the mesh degraded without stabilization. (*Id.*). Dr. Mays's results showed that all of the resins degraded in a similar manner. (*Id.*). Specifically, the specimens started to degrade around 230–250 degrees Celsius and nearly completely degraded at 400 degrees Celsius. (*Id.*). Dr. Mays noted that the Lynx product showed slightly better thermal stability than the others. (*Id.*). Based on this testing, Dr. Mays concludes that anti-oxidant stabilizers delay thermo-oxidative degradation, but do not eliminate it; therefore, polypropylene will always degrade in an oxidative environment like the human body. (*Id.* at 43).

[15] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

First, BSC argues that Dr. Mays's opinions should be excluded because his TGA did not replicate the in vivo environment. Specifically, BSC points out that Dr. Mays's TGA was conducted at temperatures well over 200 degrees Celsius when the human body is only approximately 37 degrees Celsius. (*See* BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Jimmy W. Mays, Ph.D. ("BSC's Mem. re: Mays") [Docket 41], at 7 ("TGA merely demonstrates that if you subject a plastic to a high enough temperature in air, it will degrade.")). In response, the plaintiff explains that TGA is "not intended to mimic the in vivo environment," but instead "is used as a model and provides predictive information that is particularly useful for product lifetime assessments." (Pl.'s Mem. in Opp'n to Def.'s Mot. to Exclude the Ops. & Test. of Pl.'s Expert [Docket 73], at 7).

Dr. Mays connects the TGA results to his ultimate conclusions regarding BSC's products in two places in his expert report:

> It should be noted that in the TGA experiments increasing temperature of the polypropylene in the presence of oxygen leads to degradation, which can be delayed but not eliminated by the presence of an anti-oxidant stabilizer packing. Polypropylene degradation also occurs isothermally inside the body. Here, too, polymer degradation may be slowed but not eliminated by the use of antioxidants.
> . . .
> Note that polypropylene always undergoes thermo-oxidative degradation in these experiments; the effect of anti-oxidant is only to delay the process. Likewise, the degradation of polypropylene exposed to an oxidative environment, such as the human body, can be delayed but not prevented through use of anti-oxidants.

(Ex. B, Mays Report [Docket 41-2], at 32, 43). The problem with these conclusions is one of fit. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."). Dr. Mays produced certain results while testing polypropylene at very high temperatures. He then somehow concludes that the same results will occur inside the human body at much lower temperatures, without providing any explanation or support for his opinion. "Rule 702's 'helpfulness' standard requires a valid scientific connection

to the pertinent inquiry as a precondition to admissibility." *Id.* at 591–92. Here, Dr. Mays has failed to connect his TGA results to the pertinent inquiry, which is whether the Advantage Fit degrades inside the human body. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 41] is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.[16]

G. Russell Dunn, Ph.D.

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies, LLC, a company which focuses on process and product design issues, process and product safety, and polymer product analysis. Broadly, Dr. Dunn opines that BSC mesh devices are defective because the polypropylene mesh used in these devices undergoes oxidative degradation. BSC contends that Dr. Dunn is unqualified to opine on polypropylene pelvic mesh devices and that the testing he conducted is unreliable.

First, BSC argues that Dr. Dunn is not qualified to offer opinions concerning the design, risk management, or manufacture of polypropylene mesh devices. In support of this argument, BSC highlights Dr. Dunn's lack of experience with medical devices. In response, the plaintiff first notes that this court rejected certain *Daubert* objections to Dr. Dunn in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710–11 (S.D. W. Va. 2014). However, Ethicon did not object to Dr. Dunn's qualifications in *Huskey*, as BSC has done here. The plaintiff also contends that the principles Dr. Dunn relies on are not specific to any kind of product but instead apply to the development of polymer products generally, which includes the development of medical devices.

"The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378,

[16] By excluding all of Dr. Mays's TGA opinions as irrelevant, I need not address BSC's arguments regarding the anti-oxidant removal process. (*See* BSC's Mem. re: Mays [Docket 41], at 8–9).

391 (D. Md. 2001) (finding an expert who is a mechanical engineer "not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering" and listing numerous cases with similar findings). "Although Rule 702 does not require [Dr. Dunn] to be 'precisely informed about all details of the issue raised in order to offer an opinion,' *Lorillard*, 878 F.2d at 799 (citations omitted), it also does not provide an open forum for expert testimony that will not assist the trier of fact." *Wright v. Brown*, 993 F.2d 1541, *2 (4th Cir. 1993) (unpublished table decision).

BSC cites to various admissions in Dr. Dunn's deposition evidencing his complete lack of experience with medical devices outside of litigation. (*See* BSC's Mot. to Exclude the Ops. & Test. of Russell Dunn, Ph.D. & Mem. of Law in Supp. ("BSC's Mot. re: Dunn") [Docket 42], at 5–6). For example, Dr. Dunn's company, Polymer Chemical Technologies, LLC, has been involved in over 200 projects focusing on polymer product design; however, none of these projects has involved a medical device. (*See* Ex. B, Dunn Dep. [Docket 42-1], at 10:12–15). Dr. Dunn also teaches five different chemical engineering courses at Vanderbilt University; however, he has never taught a course specific to medical devices or polypropylene. (*See id.* at 12:14–13:6). Similarly, Dr. Dunn states that he has a "tremendous amount of experience" assessing risk through Failure Mode and Effects Analysis ("FMEA"), but then admits that he has "never been involved in developing an FMEA for a medical device." (*Id.* at 273:8–25.). Finally, Dr. Dunn has authored many publications throughout his career; however, not one of these publications examines medical devices or how polypropylene behaves as part of a medical device. (*See id.* at 99:13–20).

All of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in BSC's devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not

an expert in biomaterials or biocompatibility, and that he is not qualified to opine on the way polypropylene may affect the body physiologically. (*See id.* at 24:17–18, 152:12–14, 153:15–17). Even if Dr. Dunn relies on general engineering principles that apply to polymer products across the board, the opinions set forth in his expert report are clearly outside the scope of basic engineering. *See Shreve*, 166 F. Supp. 2d at 392 ("Unless he is to testify only to general engineering principles that any mechanical engineer would know, the engineer must possess some special skill, knowledge or experience, concerning the particular issue before the court." (quotation marks and citation omitted)). Unable to draw on some special skill, knowledge, or experience related to medical devices, Dr. Dunn's opinions, including those based on his testing of BSC products, will not be helpful to the trier of fact as required by Federal Rule of Evidence 702. Furthermore, Dr. Dunn's testing lacks sufficient indicia of reliability because he failed to follow a written protocol or utilize a sufficiently large sample size. (BSC's Mot. re: Dunn [Docket 42], at 9-13); *see also Daubert*, 509 U.S. at 594 (stating "the court ordinarily should consider the known or potential rate of error"). I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case, and his opinions are unreliable, and therefore, **EXCLUDED**. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 42] is **GRANTED**.

H. Scott Guelcher, Ph.D.

Dr. Guelcher is a chemical engineer offered by the plaintiff to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Broadly, BSC contends that Dr. Guelcher's opinions on oxidative degradation should be excluded because the testing he relies upon—testing completed by Dr. Dunn—is unreliable. As discussed more fully *supra*, because I **EXCLUDE** Dr. Dunn as an expert in this

case, Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are likewise **EXCLUDED**. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 43] is **GRANTED**.

I. William Porter, M.D.

The plaintiff offers Dr. William Porter, a urogynecologist, as an expert witness on the specific causation of Ms. Wilkerson's injuries. In moving to exclude Dr. Porter's opinions, BSC argues that Dr. Porter's expert report goes beyond specific causation and into subject matter about which he is unqualified to provide expert opinions. Additionally, BSC contends that Dr. Porter did not conduct a proper differential diagnosis, and as a result, his specific causation opinion about Ms. Wilkerson is unreliable.

Before turning to these issues, I address BSC's procedural argument that the court should strike the opinions contained in Dr. Porter's First Revised Rule 26 Expert Report ("Amended Report"), (Ex. 1, First Revision: Rule 26 Expert Report of Dr. William Porter, M.D. [Docket 63-1]), thus limiting Dr. Porter's opinions to those contained in his original expert report, (Ex. O, Rule 26 Expert Report of Dr. William Porter, M.D. [Docket 44-1]). In the Amended Report, provided to BSC just before Dr. Porter's deposition and well after the deadline for expert disclosures, Dr. Porter elaborated on and adjusted his specific causation opinions based on his examination of Ms. Wilkerson earlier that day. BSC contends that this information must be excluded as untimely under Federal Rule of Civil Procedure 37.

Rule 37 provides if a party fails to properly disclose an expert's opinions, the party cannot use the omitted information "to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). To determine whether the late service of the Amended Report is "substantially justified" or

"harmless," as the plaintiff maintains, I must consider the following factors:

> (1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party's failure to name the witness before trial; and (5) the importance of the testimony.

Hoyle v. Freightliner, LLC, 650 F.3d 321, 329 (4th Cir. 2011). Although the surprise caused to BSC by the Amended Report was not insignificant—given that Dr. Porter's amendments were based on his examination of Ms. Wilkerson, which took place just hours before the deposition—I find that the remaining factors weigh in favor of allowing the Amended Report in these circumstances. First, by fully deposing Dr. Porter on this new information, BSC had an opportunity to cure the surprise. Second, because trial has not yet been scheduled, there is no concern for its disruption. Third, Dr. Porter could not have included this new information in his original report, dated October 29, 2014, because at that time, he had not yet personally examined Ms. Wilkerson. And finally, the new information contained in Dr. Porter's Amended Report is important because it affects his differential diagnosis. For these reasons, I find any failures in the original report harmless and consider Dr. Porter's Amended Report, including his handwritten edits, in my review of BSC's challenges to his expert opinions.

1. Opinions Regarding Mesh Degradation

First, BSC contends that Dr. Porter, who has no experience in polymer science or biomaterials, lacks the qualifications necessary to opine on the degradation of mesh or its tendency to shrink, contract, curl, fold, wrinkle, fragment, or cause pain in general. I disagree. A witness can be qualified as an expert "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. As I have held in previous cases, a urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on how the product reacts inside the body. *See, e.g., Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *72

(S.D. W. Va. 2014), *available at* 2014 WL 5320566 (finding a urogynecologist who has performed almost 3,000 sling procedures over the last twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infections). Dr. Porter's experience in the area of pelvic medicine is undeniable: Over the last 15 years, he has performed nearly 3,000 surgeries using pubovaginal slings, both synthetic and xenographic, (Ex. 1, Amended Report ¶ I [Docket 63-1]); several thousand POP surgeries using native tissue and other materials, (*id.*); and has removed and repaired slings, (*id.*). That he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about "what's happening at the molecular level." (BSC's Mot. & Mem. in Supp. to Exclude the Ops. & Test. of William Porter, M.D. ("BSC's Mot. re: Porter") [Docket 44], at 5). Rather, he considers mesh degradation on a large scale, focusing on the ways a polypropylene mesh product can change after implantation in the human body. His fifteen-year career as a pelvic surgeon qualifies him to render these opinions to the extent that they are applicable to his differential diagnosis in this specific case.

2. Specific Causation Opinion

The primary focus of Dr. Porter's Amended Report is his opinion that "the Boston Scientific Advantage mesh product implanted into Hanna Wilkerson caused Hanna Wilkerson injuries." (Ex. 1, Amended Report ¶ VI [Docket 63-1]). In arriving at this opinion, Dr. Porter explains that he conducted a differential diagnosis. A differential diagnosis is a technique that "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (internal citation omitted). It involves "identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Id.* A differential diagnosis, if reliable, passes scrutiny under *Daubert*. Here, BSC argues the

differential diagnosis that Dr. Porter applied to arrive at his opinion was unreliable because after examining Ms. Wilkerson, Dr. Porter "back[ed] off many of his opinions." (BSC's Mot. re: Porter [Docket 44], at 18). Specifically, according to BSC, Dr. Porter testified that after examining Ms. Wilkerson, he no longer believes that she is experiencing vaginal pain or dyspareunia from the sling. (*See id.* at 18 (citing to Dr. Porter's deposition testimony)).

My review of Dr. Porter's Amended Report and deposition testimony indicates that BSC is correct in its interpretation of Dr. Porter's differential diagnosis—after his examination of Ms. Wilkerson, Dr. Porter "eliminated vaginal pain" and "dyspareunia" as complications resulting from the mesh, and limited her complications to "suprapubic pain" located at one of her incision cites. (Ex. AA, Porter Dep. [Docket 44-1], at 14:10–23). While this change in opinion gives BSC robust material for Dr. Porter's cross-examination, it does not create grounds for exclusion. *See McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995) (stating that "faults in [an expert's] use of differential etiology as a methodology . . . go to the weight, not the admissibility of his testimony"); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265–66 (4th Cir. 1999) (citing to *McCullock*'s principle that "perceived faults in doctor's differential diagnosis are matters for cross-examination that do not affect admissibility"). What matters for the purposes of *Daubert* is whether a physician's differential diagnosis "utterly fails to consider alternative causes or fails to offer why the proffered alternative cause was not the sole cause." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001).

Here, BSC has not put forth any alternative causes for Ms. Wilkerson's suprapubic pain that Dr. Porter does not address. Based on his examination of Ms. Wilkerson, his review of her medical records, his knowledge of mesh complications, and his experience with other patients, Dr. Porter was able to rule out the other possible risks for her pain, including Ms. Wilkerson's

previous hysterectomy and postoperative scarring and granulation tissue from her vaginal repair. (*See* Ex. 3, Porter Dep. [Docket 63-3], at 36:22–37:2 (explaining that the pain is "exactly where the sling would be exiting through the fascia," which is "consistent with what [he's] seen [in] other people"); *id.* at 37:11–17 (stating that the contraction of mesh, rather than a hysterectomy, explains why pain would be "at the exit point"); *id.* at 41:1–25 (referring to previous medical records indicating "tender nodular area over the left trocar site")). Therefore, I find his differential diagnosis sufficient. *See Westberry*, 178 F.3d at 255 ("The alternative causes suggested by a defendant affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony, unless the expert can offer *no* explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause." (internal quotation marks and citations omitted)).

For the above reasons, BSC's Motion to Exclude the Opinions and Testimony of Dr. Porter [Docket 44] is **DENIED**.

J. Richard Trepeta, M.D.

The plaintiff has indicated that she does not intend to call Dr. Trepeta at trial. (Disclosure Required by Pretrial Order # 121 [Docket 53]). Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [Docket 45] is **DENIED as moot**.

K. Vladimir Iakovlev, M.D.

Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. Dr. Iakovlev offers both general and specific causation opinions with regard to the body's response to mesh from a pathologic perspective. BSC argues that Dr. Iakovlev's general causation opinions should be excluded because he relies on specimens other than Ms. Wilkerson's. BSC also argues that

Dr. Iakovlev's specific causation opinions should be excluded because he did not review the pathology for this particular plaintiff, Ms. Wilkerson.

1. General Causation

BSC contends that this court should "exclude Dr. Iakovlev's opinions on specimens other than each plaintiff's." (BSC's Mot. to Strike and Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. [Docket 50], at 4). Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. (*See* Ex. 2, Iakovlev Report [Docket 50-2], at 2, 5). However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiff's counsel provided approximately 70% of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed. (Ex. 41, Iakovlev Dep. [Docket 75-3], at 38:12–39:21). Dr. Iakovlev "has given no explanation as to whether [his] is a representative sample size or how he chose the particular explants analyzed." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014). "Therefore, I have no information as to the 'potential rate of error' inherent in [his] observations." *Id.* (citing *Daubert*, 509 U.S. at 594).

In response, the plaintiff contends that Dr. Iakovlev's methodology is sound because it has been subjected to the publication and peer-review process. This past year, Dr. Iakovlev published two articles in peer reviewed journals about his mesh explant research. *See* Vladimir V. Iakovlev, et al., *Pathology of Explanted Transvaginal Meshes*, 8 Int'l J. Medical, Health, Biomedical and Pharmaceutical Engineering No. 9 (2014); Robert Bendavid, et al., *Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain*, 5 Int'l J. Clinical Med. 799, 799–810 (2014).

However, "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability," and is not dispositive. *Daubert*, 509 U.S. at 593–94. In his most recent deposition, Dr. Iakovlev does not explain how the explant samples were chosen and neither do these articles. Therefore, despite publication, the court's concerns with regard to the data pool remain. Likewise, upon review, I find the plaintiff's remaining arguments to be without merit. Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

2. Specific Causation

It is unclear whether Dr. Iakovlev intends to offer a specific causation opinion in this case because the court has not been provided with an expert report from Dr. Iakovlev specific to Ms. Wilkerson. Regardless, BSC's Exhibit 1 indicates that Ms. Wilkerson's case is one where Dr. Iakovlev did not review any pathology. (Ex. 1 [Docket 50-1], at 5). In *Eghnayem v. Boston Scientific Corp.*, I found Dr. Iakovlev's specific causation opinions reliable based on his "morphological differential diagnosis," which included an examination of the plaintiff's explanted mesh. __ F. Supp. 3d __, *46 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. In this case, there is no evidence that Dr. Iakovlev examined Ms. Wilkerson's explanted mesh or performed a physical examination. Assuming Dr. Iakovlev seeks to offer specific causation opinions, such opinions are not sufficiently reliable under *Daubert* and are thus **EXCLUDED**.

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 50] is **GRANTED**.

V. The Plaintiff's *Daubert* Motions

In this case, the plaintiff seeks to limit or exclude the expert opinions of Drs. Ricardo

Caraballo, Gary L. Winn, Christine Brauer, Stephen Spiegelberg, and Stephen F. Badylak.

A. Ricardo Caraballo, M.D.

Dr. Ricardo Caraballo is a board-certified obstetrician-gynecologist who practices in the areas of urogynecology, female pelvic medicine, and reconstructive surgery. He has "extensive experience" with BSC's Advantage Fit product, and furthermore, he has taught the surgical procedure of implanting the Advantage Fit to other physicians around the country. (Ex. A, Caraballo Report [Docket 38-1], at 1). In broad terms, BSC offers Dr. Caraballo as an expert witness on the safety and effectiveness of the Advantage Fit and the adequacy of its DFU. (*See generally id.*). The plaintiff argues that Dr. Caraballo lacks the qualifications to render these opinions and failed to apply a reliable methodology. I address the plaintiff's objections in turn.

1. Opinions on the Safety and Effectiveness of the Advantage Fit

First, the plaintiff argues that Dr. Caraballo's opinions on safety and effectiveness focus on midurethral slings in general, rather than the Advantage Fit specifically, and as a result, these opinions should be excluded. This argument is unpersuasive for several reasons.

Daubert requires an expert's opinion to have "a valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 591–92. Dr. Caraballo has established such a connection between his research on midurethral slings in general and his opinion on the Advantage Fit. Put simply, as Dr. Caraballo explains, the midurethral slings he considered are "similar" to the Advantage Fit for all purposes relevant to his opinion. (Ex. B, Caraballo Dep. [Docket 38-2], at 62:22–23). The other midurethral slings he considered are made of Type I polypropylene mesh, (*id.* at 21:2–3), which is the same material that BSC used to manufacture the Advantage Fit, and, according to Dr. Caraballo, the products "behave in a similar fashion," (*id.* at 60:23–24). Thus, given the lack of studies specific to the Advantage Fit, (*id.* at 63:11–17), Dr. Caraballo consulted

the long-term data on Type I polypropylene midurethral slings to inform his opinions on the Advantage Fit. (Ex. A, Caraballo Report [Docket 38-1], at 4). The plaintiff has not identified any difference between the Advantage Fit and other Type I mesh products that would make Dr. Caraballo's comparison unreasonable or unreliable. Accordingly, I do not find his consideration of the literature for Type I midurethral slings fatal to the admissibility of his opinions on the safety and effectiveness of the Advantage Fit.

Furthermore, Dr. Caraballo's experience as a pelvic surgeon supplements the scientific connection between his opinion on other Type I mesh products and his opinions on the Advantage Fit. Though the plaintiff attempts to undermine Dr. Caraballo's qualifications by pointing to several facts about the Advantage Fit that Dr. Caraballo "doesn't know," (Pl.'s Mot. to Exclude Certain Ops. & Test. of Dr. Ricardo Caraballo [Docket 38], at 6–7), Dr. Caraballo's experience with SUI products cannot be denied. He has implanted approximately seventy to eighty Advantage or Advantage Fit products per year over the course of his career. (Ex. 2, Caraballo Dep. [Docket 57-2], at 49:7–9). He has taught other physicians how to perform the surgery. (Ex. A, Caraballo Report [Docket 38-1], at 1). And importantly, he has used midurethral slings designed by other manufacturers, allowing him to compare their performance to that of the Advantage Fit. (Ex. B, Caraballo Dep. [Docket 38-2], at 30:22–31 (comparing the TVT to the Advantage)). This experience, along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit. *See In re Mentor Corp. ObTape Transobturator Sling Products Liab. Litig.*, 711 F. Supp. 2d 1348, 1370–71 (M.D. Ga. 2010) (citing a doctor's experience with implanting a particular mesh product, along with his experience implanting comparable slings and his review of the scientific literature, as reasons to qualify him as an expert witness). Any criticisms about what Dr. Caraballo "doesn't know" about

the Advantage Fit can be raised at cross-examination. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct.").

This part of the plaintiff's motion against Dr. Caraballo is **DENIED**.

2. Opinions on the DFU

Next, the plaintiff argues that Dr. Caraballo does not have the qualifications necessary to opine on the DFU of the Advantage Fit. To support this contention, the plaintiff points to Dr. Caraballo's lack of professional experience with drafting DFUs, as well as his deposition testimony, where he stated he "almost never look[s] at the DFU" to become informed about the complications associated with a product. (Ex. B, Caraballo Dep. [Docket 38-2], at 190:5–6). In response, BSC states that Dr. Caraballo "does not intend to testify that the DFUs comply with regulatory requirements or are adequate from the perspective of an expert in warning labels or FDA regulations." (BSC's Mem. in Opp'n to Pl.'s Mot. to Exclude Certain Ops. & Test. of Dr. Ricardo Caraballo [Docket 57], at 7). Rather, he "intends to offer a clinician's perspective that the DFU[] provide[s] accurate statements of risks and complications he has encountered in his practice and his review of medical literature." (*Id.*).

Although Dr. Caraballo has no experience with drafting DFUs, he has demonstrated experience with the Advantage Fit and the risks associated with its use. *See supra* § V.A.1. Based on this experience, I find him qualified to testify about whether the risks mentioned in his expert report are in fact warned about in the DFU. However, Dr. Caraballo's opinion testimony on the DFU must stop there. A doctor who has no background in the requirements of a DFU is not qualified to opine that it "*adequately*" warns of "*all* of the risks and complications," (Ex. A, Caraballo Report [Docket 38-1], at 6 (emphasis added)), merely because it mentions risks he

personally knows about or has observed in his practice. *See, e.g.*, *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, at *70 (S.D. W. Va. 2014), *available at* 2014 WL 5320566 (excluding a urologist as unqualified to opine that a DFU "adequately warned" of "all [] potential complications"). Likewise, he is not qualified to opine about what risks are "obvious" or "inappropriate" for a DFU. (*Id.* at 6). Accordingly, without additional expertise in the specific area of product warnings, these opinions on the DFU are **EXCLUDED**. The plaintiff's motion on this point is thus **DENIED in part** and **GRANTED in part**.

3. Opinions on the Foreign Body Response and Mesh Degradation

The plaintiff also argues that Dr. Caraballo's opinions on the foreign body response and mesh degradation should be excluded because Dr. Caraballo is not an expert in the field of biomechanics and has not reviewed contrary literature. Again, in light of Dr. Caraballo's clinical background as a pelvic floor surgeon and his years of experience implanting SUI mesh products, I find him qualified to discuss these matters. I do not, however, find these opinions supported by a reliable methodology.

Several courts have held that an expert's opinion is unreliable when he fails to acknowledge or account for contrary scientific literature. *See In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 389, 425 (S.D.N.Y. 2005) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable."); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1087 (D. Kan. 2002), *aff'd*, 356 F.3d 1326 (10th Cir. 2004) ("[O]btaining information from sources that support, refute or are neutral regarding the hypothesis is appropriate to minimize the likelihood of a false conclusion."); *Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("[A] reliable expert would not ignore contrary

data . . . ."). I have also adhered to this approach, excluding expert opinions when the expert did not explain his reason for discounting or disagreeing with contrary literature. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-5762, 2014 WL 4851989, at *13 (S.D. W. Va. Sept. 29, 2014) (excluding the opinion of Dr. Margolis because his only explanation for discounting contrary studies was "that's not what I have seen, read, studied, observed, and that's not biologically plausible"). Here, Dr. Caraballo has cited to some sources in support of his opinion that mesh does not degrade in response to the foreign body reaction. But he chose to disregard literature that indicates otherwise:

> Q: . . . . And are you aware of medical and scientific literature concluding that polypropylene degrades in the body?
> [objection omitted]
> A: I have heard of there being some of those -- that literature. To be perfectly honest, *I haven't looked at it with any significant degree*. The reason being the degradation to me, unless it's shown otherwise, I have not seen it.

(Ex. B, Caraballo Dep. [Docket 38-2], at 190:24–191:9). Dr. Caraballo's decision to ignore the contesting literature—with no explanation for that decision other than the fact that he has not "seen" degradation—warrants exclusion of these opinions. Accordingly, the plaintiff's motion on this point is **GRANTED**.

4. Opinions on Mesh Shrinkage or Contraction

Next, the plaintiff objects to Dr. Caraballo's opinion that polypropylene mesh does not shrink or contract in the body on the grounds that Dr. Caraballo has not tested or measured explants. Looking at Dr. Caraballo's methodology as a whole, I do not find the omission of these tests dispositive. Dr. Caraballo relies on his clinical experience, during which he has seen no evidence of mesh contracture, and a peer-reviewed article, which found no evidence of mesh contraction after monitoring sixty women over a period of fifty-two months. (Ex. A, Caraballo Report [Docket 38-1], at 7 (citing Hans Peter Dietz et al., *Mesh contraction: myth or reality?*,

204 Am. J. Obstetrics & Gynecology 173, 173 (2011))). Furthermore, he provides a specific and reasoned explanation for why he finds contrary literature unpersuasive: "Literature suggesting that polypropylene mesh contracts relies upon ultrasound images from hernia repairs. These ultrasound images could not accurately distinguish between mesh contraction and tissue contraction." (*Id.*). This methodology satisfies *Daubert*, and I therefore **DENY** the plaintiff's motion on this issue. *See Daubert*, 509 U.S. at 592–93 (stating that the district court's gatekeeper role requires a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid").

5. Opinions About the MSDS

Finally, the plaintiff argues that Dr. Caraballo is not qualified to offer any opinions on the MSDS. Dr. Caraballo's opinion, in short, is that the MSDS "is irrelevant to the clinician's choice of device in treating patients with SUI," and that he "ha[s] not seen any evidence that the medical application caution was added because of any scientific or safety concerns." (Ex. A, Caraballo Report [Docket 38-1], at 8). With respect to the first part of this opinion, I find Dr. Caraballo, who has extensive experience implanting various mesh products in his patients, qualified to testify as to what a physician would or would not consider in determining the risks of a product.

The second part of the opinion, however, is not admissible under *Daubert*, which bars expert testimony based on "belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). Dr. Caraballo, who has no knowledge about a manufacturer's considerations when drafting an MSDS, attempts to opine that because he did not see any evidence suggesting the MSDS has scientific roots, none exists. Such a speculative leap is improper for expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

Therefore, this opinion is **EXCLUDED**.

To summarize, the plaintiff's Motion to Exclude Certain Opinions and Testimony of Dr. Ricardo Caraballo [Docket 38] is **GRANTED in part** and **DENIED in part**.

B. Gary L. Winn, Ph.D.

Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University. Dr. Winn offers expert "opinions with regard to the nature and purpose of Material Safety Data Sheets (MSDS) generally, and specifically as to the MSDS for the polypropylene used by [BSC] in the manufacture of its pelvic mesh products." (Ex. A, Winn Report [Docket 39-1], at 1). The plaintiff argues that Dr. Winn's opinions should be excluded entirely, consistent with this court's decisions in *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *63 (S.D. W. Va. 2014), *available at* 2014 WL 5320566, and *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *61 (S.D. W. Va. 2014), *available at* 2014 WL 5461991, because his expert report is identical to the reports filed and excluded in those two cases.[17] In response, BSC contends that it "should be allowed to offer Dr. Winn's testimony and opinions to rebut MSDS related evidence presented by the Plaintiffs at trial." (BSC's Mem. in Opp'n to Pl.'s Combined Mots. to Exclude the Ops. & Test. of Gary L. Winn, Ph.D. [Docket 60], at 17). Specifically, BSC points to the transcripts from *Tyree* and *Eghnayem*

[17] In *Tyree*, I ruled as follows:

> In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. Dr. Winn concludes that raw polypropylene is not hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form. Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

2014 WL 5320566, at *63; *see also Eghnayem*, 2014 WL 5461991, at *61 (quoting *Tyree*).

where the plaintiffs' experts testified about the MSDS. (*Id.* at 15–16).

BSC has not presented any new arguments to convince me that Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiff presents at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions for trial.

C. Christine Brauer, Ph.D.

Dr. Brauer is the President of Brauer Device Consultants, LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. The plaintiff seeks to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory requirements for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. (*See* Ex. 2, Brauer Dep. [Docket 83-2], at 8:13–20). "Anticipating that the Court will adopt its prior rulings and exclude FDA evidence here," BSC does not contest the plaintiff's motion with regard to the FDA report. (BSC's Resp. in Opp'n to Pl.'s Mot. to Exclude or Limit the Test. of Expert Christine Brauer, Ph.D. [Docket 59], at 1). In *Sanchez v. Boston Scientific Corp.*, I ruled as follows:

> I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, at 753–56 (S.D. W. Va. 2014). Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. *See, e.g., Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 102699, at *22 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative interaction with state tort laws.") (internal reference omitted); Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. July 1, 2013), [Docket 309], at 3–4 ("Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective . . . . Because the FDA 510(k) process does not go to whether the [mesh] products are safe and effective and the

> 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues."); Mem. Op. & Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. June 27, 2013) [Docket 302], at 3–4 (holding that evidence regarding the 510(k) process and enforcement should be excluded under Rule 403); Mem. Op. & Order, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D. W. Va. May 12, 2014 [Docket 223], at 1 ("This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA's 510(k) process . . . In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to the safety and efficacy of medical devices and because of the potential to mislead and confuse the jury."). Accordingly, I **FIND** that Dr. Brauer's opinions should be excluded in their entirety.

No. 2:12-cv-05762, 2014 WL 4851989, at *36–37 (S.D. W. Va. Sept. 29, 2014). Accordingly, the plaintiff's motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiff contends that it "is nothing more that [sic] her FDA Report under a different cloak." (Pl.'s Reply in Supp. of Pl.'s Mot. to Exclude or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket 83], at 4). Therefore, in the plaintiff's view, Dr. Brauer's supplemental report should be excluded for the same reasons her FDA report was previously excluded, given that the two reports are "substantially identical." (Pl.'s Mot. & Mem. to Exclude or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket 40], at 2). I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. For example, in her supplemental report, Dr. Brauer states: "It is an industry standard for a manufacturer of certain new or modified medical devices to demonstrate that its new device is substantially equivalent to another legally marketed device, and is as safe and effective as other similar devices prior to marketing in this U.S." (Ex. 3, Brauer Report [Docket 40-4], at 4). This "industry standard" clearly describes the FDA 510(k) process, which

Dr. Brauer admits in her deposition. (*See* Ex. 2, Brauer Dep. [Docket 83-2], at 43:7–18 ("Q: I'm talking about this one sentence . . . That's the 510(k) process; correct? A: That is the 510(k) process.")).

Also, Dr. Brauer states that medical devices are grouped into three categories, which she labels as "Low-Risk," "Moderate Complexity and Risk," and "Complex, High Risk." These "industry standard" categories perfectly align with the three regulatory classes established by the Medical Device Amendments, another fact Dr. Brauer admits. (*See id.* at 48:13–9 ("Q: The low-risk medical devices are Class I devices. The moderate complexity and risk medical devices are Class II devices; correct? A: For most products, they probably would fit in that way, yes.")).

BSC contends that Dr. Brauer's industry standard opinions do not require presenting FDA evidence to the jury because the industry standards are broader than FDA regulations. However, Dr. Brauer explains that FDA regulations are part of industry standards, and, therefore, any evidence with regard to industry standards would require reference to the FDA, whether it is disguised or not. (*See id.* at 34:13–23 ("A: When you do it with industry, you want to make sure that your regulatory requirements are met, but also that certain customer needs are met. So there's a little different of a slant, but it's still the primary same content. Q: So in both ways you're trying to comply with FDA regulations? A: In part. In both ways you're trying to comply with FDA regulations because that's part of it.")).

Furthermore, although she cites a few standards issued by the International Organization for Standardization ("ISO"), including ISO 13485, in her supplemental report, when asked about additional standards during her deposition, Dr. Brauer cannot recall any specific standards, other than ISO 13485. (*Id.* at 35:15–21). And when pressed on whether there is an ISO standard that requires manufacturers to submit adverse events to the FDA, Dr. Brauer is unable to articulate an

identifiable ISO standard to support her premise. (*See id.* at 46:18–47:1 ("Q: It says that it's an industry standard to submit certain reports to adverse events to the FDA. A: That's correct. Q: So there's no actual standard that says that; correct? A: I don't believe it's that specifically stated in the ISO standard.")). Dr. Brauer's inability to identify an applicable standard renders her opinion unreliable. *See Lasorsa v. Showboard: The Mardi Gras Casino*, No. 07-4321, 2009 WL 2929234, at *5 (D.N.J. Sept. 9, 2009) ("Without a reliable, objective basis for [expert] testimony, stemming from identifiable industry standards, codes, publications or training, it must be precluded under Rule 702.")

Dr. Brauer's deposition testimony reveals that her true area of expertise is the regulatory field, which is why she was originally retained to write a regulatory report. (*See id.* at 12 ("I believe the first contact was regarding FDA regulation of medical devices.")); *see also Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 691 F. Supp. 2d 448, 476 (S.D.N.Y. 2010) (finding an expert's opinions with regard to industry standards unreliable when not "ground[ed] in his knowledge of the custom and practice of the industry"). There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiff's Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D [Docket 40] is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety.

D. Stephen Spiegelberg, Ph.D.

Dr. Spiegelberg is the president and co-founder of Cambridge Polymer Group, Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer communities. Broadly, Dr. Spiegelberg opines that BSC's pelvic mesh products "are appropriate for their intended use in design and

manufacture." (Ex. B, Spiegelberg Report [Docket 47-2], at 4). The plaintiff objects to the following general causation opinions offered by Dr. Spiegelberg: (1) general causation opinions regarding the position statements of medical organizations; (2) any matters related to the FDA clearance process; (3) opinions regarding the presence of black specks in BSC's mesh; and (4) opinions based on Fourier Transform Infrared Spectroscopy ("FTIR") and Energy Dispersive Spectrometry ("EDS"). I address these objections in turn.

1. Position Statements

First, the plaintiff argues that Dr. Spiegelberg's opinions regarding position statements should be excluded because (1) they are not contained in his expert report; (2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. In response, BSC states that Dr. Spiegelberg does not offer opinions regarding position statements in either his expert report or his most recent deposition. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions the plaintiff seeks to exclude. Accordingly, the plaintiff's motion with regard to position statements is **DENIED as moot**.

2. FDA

Next, the plaintiff contends that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiff's motion with regard to the FDA is **GRANTED**. BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on ISO standards based on his "extensive experience in the field of medical device analysis and design." (BSC's Resp. in Opp'n to Pl.'s Mot. to Exclude the Ops. & Test. of Dr. Stephen Spiegelberg, Ph.D. [Docket 66], at 6). I agree. Dr. Spiegelberg's current work revolves around medical device development and

consultation. (*See* Ex. B, Spiegelberg Report [Docket 47-2], at 2). He is also the Task Force Chairman for ASTM standards involving the cleanliness of biomedical devices and characterization methods for polymers. (*Id.* at 3). Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiff's motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

3. Black Specks/Spots

Next, the plaintiff argues that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr. Spiegelberg states: "I have reviewed information suggesting 'black spots' may appear in the polypropylene. These 'black spots' are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh." (Ex. B, Spiegelberg Report [Docket 47-2], at 12). Dr. Spiegelberg elaborated on this conclusion in his deposition:

Q: And if I remember – do you remember what your opinion was in regard to black specks?

A: I do.

Q: Can you tell me?

A: The black specks that I observed in the meshes were not black specks per se, as in terms of inclusions, rather were just reflections that are often inherent in circular surfaces.

Q: And did you perform independent testing to verify that?

A: Yes, I did.

Q: And could you describe that to me?

A: You take the mesh and place it in an optical microscope, and then rotate

> the mesh under the optical microscope and see if the black specks move or disappear, which they did.

(Ex. D, Spiegelberg Dep. [Docket 66-1], at 17:22–18:14). The plaintiff contends that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by the plaintiff's expert, Dr. Dunn, nor did he take his own photographs. However, in his deposition, Dr. Spiegelberg testified that he did review Dr. Dunn's photographs. (*Id.* at 19:15). And whether Dr. Spiegelberg took his own photographs does not sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black spots are better suited for cross-examination. Accordingly, the plaintiff's motion with regard to black specks/spots is **DENIED**.

4. FTIR/EDS

Last, the plaintiff seeks to limit Dr. Spiegelberg's general causation opinions based on his FTIR and EDS testing. However, the plaintiff also states that Dr. Spiegelberg's "admissions regarding the limitations of these techniques may also be grounds for cross-examination," and seeks only "qualification or explanation of the limitations inherent to these techniques" in order to avoid misleading or confusing the jury. (Pl.'s Mot. & Mem. in Supp. of Mot. to Exclude the Test. & Ops. of Dr. Stephen Spiegelberg, Ph.D. [Docket 47], at 11). The plaintiff will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiff's motion with regard to Dr. Spiegelberg's FTIR and EDS testing is **DENIED**.

In sum, the plaintiff's Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [Docket 47] is **GRANTED in part** and **DENIED in part**.

E. Stephen F. Badylak, D.V.M., Ph.D., M.D.

Dr. Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine,

Director of the Center for Preclinical Studies, and a full Professor with tenure with the Department of Surgery at the University of Pittsburgh. Broadly, Dr. Badylak opines that the polypropylene mesh used in BSC's pelvic mesh products is biocompatible and safe for use in the human body. The plaintiff asks the court to exclude Dr. Badylak's (1) opinions related to the risk/benefit analysis or the safety and efficacy of BSC devices; and (2) opinions related to oxidative degradation.

1. Risk/Benefit Analysis or Safety & Efficacy

First, the plaintiff contends that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. In support of their argument regarding scientific literature, the plaintiff cites to a portion of Dr. Badylak's deposition where he "admitted" that he has not performed a "comprehensive review" of the literature related to specific BSC devices. (Pl.'s Mot. & Mem. of Law in Supp. of Their Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 48], at 7). However, Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. (BSC's Opp'n to Pl.'s Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 58], at 8; *see also* Ex. 2, Additional Materials Considered for Expert Report [Docket 48-2], at Ex. B). Furthermore, Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. (*See* Ex. 5, Badylak Dep. [Docket 48-5], at 98:22–25); *see also Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991) (explaining that "a lack of specialization does not affect the admissibility of the opinion, but only

its weight"). This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.

Similarly, the plaintiff's arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. (*See* Ex. 2, Badylak Report [Docket 57-2], at 1). The qualification requirement of Federal Rule of Evidence 702 does not necessarily require specific clinical experience implanting the device at issue. *See Thomas J. Kline, Inc. v. Lorillard*, Inc., 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion."); *see also Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *4–5 (S.D. W. Va. July 8, 2014) (finding expert qualified to offer general causation opinions despite his lack of specific experience with the product at issue). Accordingly, the plaintiff's motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

2. Degradation

Lastly, the plaintiff argues that Dr. Badylak's opinions with regard to oxidative degradation based on the scientific literature are unreliable because he contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. (*See* Ex. 5, Badylak Dep. [Docket 48-5], at 108:2–6 ("I'm aware of the literature and the discussion, I'm aware of phenomenon of oxidative changes and oxidative reactions in the body everywhere, including the surface of biomaterials such as polypropylene, so yes, I've considered that. . . . As a matter of fact, I'm on record as saying oxidative reactions occur everywhere, including the

surface of biomaterials."). However, the plaintiff omits Dr. Badylak's subsequent testimony, where he states: "What I don't believe is that these oxidative reactions at the surface of polypropylene are resulting in the degradation that's causing further problems. There's no evidence to suggest that exists." (*Id.* at 108:11–109:15). Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiff's motion with regard to degradation is **DENIED**.

The plaintiff's Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 48] is thus **DENIED**.

VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule.

VII. Conclusion

For the reasons discussed above, my rulings on BSC's motions are as follows:

Motion to Exclude the General Causation Testimony of Bruce Rosenzweig, M.D. [Docket 31] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 32] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 34] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [Docket 36] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Marvin Goldberg, Ph.D. [Docket 37] is **DENIED as moot**; Motion to Exclude

the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 41] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 42] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 43] is **GRANTED**; Motion to Exclude the Opinions and Testimony of William Porter, M.D. [Docket 44] is **DENIED**; Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [Docket 45] is **DENIED as moot**; and Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 50] is **GRANTED**.

My rulings on the plaintiff's motions are as follows:

Motion to Exclude the Opinions and Testimony of Ricardo Caraballo, M.D. [Docket 38] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [Docket 39] is **RESERVED**; Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D. [Docket 40] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Stephen Spiegelberg, Ph.D. [Docket 47] is **GRANTED in part** and **DENIED in part**; and Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 48] is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 5, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE